

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

**IN RE: BIOZORB DEVICE PRODUCTS
LIABILITY LITIGATION**

This Document Relates to: Plaintiff Beth Deuel in Case No. 1:23-cv-10579-ADB; Plaintiffs Cynthia Kresch and Kimberly Taylor in Case No. 1:23-cv-10260; and Plaintiff Pamela Gibson in Case No. 1:23-cv-10599-ADB.

Case No. 1:22-cv-11895-ADB

**DEFENDANT HOLOGIC, INC.'S MEMORANDUM IN SUPPORT OF MOTION TO
EXCLUDE OPINIONS OF PLAINTIFFS' EXPERT DR. GUY JONES**

I. INTRODUCTION

Plaintiffs disclosed radiation oncologist Dr. Guy Jones to give medical causation opinions in this litigation. But Dr. Jones has no reliable methodology for concluding that BioZorb causes injuries in patients. He does not base his opinions on any scientific studies concluding that the BioZorb is associated with an increased risk of pain or other adverse events. Instead, he relies largely on his own experience with BioZorb patients to reach his causation opinions. But he has no written record whatsoever to document this experience – he did not write or publish about it; he did not report any BioZorb adverse events to FDA; and he has no medical records from these patients. Dr. Jones’ subjective and untestable views based on memory of his personal experience fall far short of Rule 702’s requirements for a reliable scientific method. The Court should therefore exclude him from giving any “general causation” opinion.

The Court should likewise exclude Dr. Jones’ “specific causation” opinion that BioZorb injured the bellwether Plaintiffs Kimberly Taylor and Beth Deuel. Dr. Jones purports to conduct a “differential diagnosis” to reach this conclusion. Yet he fails to reliably “rule in” BioZorb as a potential cause for their injuries for the same reasons he cannot offer an admissible general causation opinion. Nor does he reliably “rule out” other causes for their conditions, given the significant rate of pain and other complications associated with breast surgery and radiation treatment even without the BioZorb. He asserts, for example, that Plaintiffs’ pain was more prolonged and localized than expected. But he offers no reliable data to support that view -- a view that is also contrary to the objective medical evidence concerning Plaintiffs’ conditions.

Finally, Dr. Jones’ opinions regarding Hologic’s marketing of the BioZorb and internal company documents should be excluded as well. Those opinions are not the proper province of expert testimony, fall outside the scope of his expertise, and are not based on reliable methods.

II. FACTUAL BACKGROUND

A. Breast Cancer Treatment and the BioZorb

Approximately 300,000 women in the U.S. are diagnosed with breast cancer each year.¹ One common treatment option, known as breast conserving therapy, entails excision of the cancerous tumor (called a “lumpectomy” or “partial mastectomy”), typically followed by radiation therapy.²

Breast conserving therapy was a major medical advance for women beyond the prior treatment, which was a total mastectomy. Unfortunately, however, breast conserving therapy is still associated with a significant background risk of complications, including chronic pain. One study, for example, concluded that at 15 months post-surgery, 31% of patients who had a lumpectomy reported pain “almost every day” or more frequently.³ Another study found that over a third of breast cancer patients reported “persistent pain” five to seven years post-treatment.⁴ A randomized controlled trial similarly found that five years after radiation therapy, 22% of patients who received accelerated partial breast radiation (“APBI”) and 22% of patients who received whole breast radiation reported either grade 1 or 2 pain (grade 3 being the highest level).⁵

¹ See American Cancer Society, *Breast Cancer Facts & Figures 2024–2025*, at 3, <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/2024/breast-cancer-facts-and-figures-2024.pdf>.

² American Cancer Society, *Breast-conserving Surgery (Lumpectomy)*, <https://www.cancer.org/cancer/types/breast-cancer/treatment/surgery-for-breast-cancer/breast-conserving-surgery-lumpectomy.html>.

³ M. Johannsen et al., *Socio-Demographic, Treatment-Related, and Health Behavioral Predictors of Persistent Pain 15 Months and 7-9 Years After Surgery: A Nationwide Prospective Study of Women Treated for Primary Breast Cancer*, 152(3) BREAST CANCER RSCH. & TREATMENT, 645, 652 (2015).

⁴ Mathias Kvist Mejdahl et al., *Persistent pain and sensory disturbances after treatment for breast cancer: six year nationwide follow-up study*, BMJ, 346 (2013).

⁵ Csaba Polgár et al., *Late side effects and cosmetic results of accelerated partial breast irradiation with interstitial brachytherapy versus whole-breast irradiation after breast*

The BioZorb, which FDA first cleared in 2012, is a three-dimensional implantable marker used to mark soft tissue at the site of a partial mastectomy. Ex. I at 1–3. It is comprised of a bioabsorbable spacer made from polylactic acid (“PLA”) that holds titanium marker clips in a three-dimensional framework. The spacer is resorbed by the body over time, leaving the marker clips to help identify the tumor site in future imaging (such as X-rays, CT scans and ultrasound). Different versions of the BioZorb were subsequently cleared by FDA on four other occasions.⁶

Studies published in respected, peer-reviewed journals have repeatedly found that the BioZorb is efficacious and has low rates of adverse effects. A large national registry (Kaufman et al.) followed 818 BioZorb patients, with a median follow-up period of 18.2 months.⁷ In the registry, both surgeons and radiation oncologists reported high satisfaction with the device and a low rate of adverse events. *See id.* at 2533–34. A study that followed 108 BioZorb patients (Cross et al.) found that the BioZorb proved useful for radiation planning in 95.7% of cases with no significant device-related complications or post-operative infections reported.⁸ Another study (Tsang et al.) followed 134 patients implanted with the BioZorb between May 2015 and February 2020 and concluded that patients were overall satisfied with the device, with only three patients (2.2%) requesting removal of the device and no patients reporting infections.⁹ *See also* Ex. J at

conserving surgery for low-risk invasive and in-situ carcinoma of the female breast: 5-year results of a randomized, controlled, phase 3 trial, LANCET ONCOL., 18(2):259–68, 263 (2017).

⁶ Ex. I (FDA clearance letters in June 2015 (BioZorb Marker), August 2015 (BioZorb LP Marker), November 2017 (BioZorb Gold), and September 2019 (BioZorb SP)).

⁷ Cary S. Kaufman et al., *A Three-Dimensional Bioabsorbable Tissue Marker for Volume Replacement and Radiation Planning: A Multicenter Study of Surgical and Patient-Reported Outcomes for 818 patients with Breast Cancer*, 28 ANNALS OF SURGICAL ONCOLOGY, no. 5, May 2021, at 2529–42, 2529.

⁸ Cross MJ, Lebovic GS, Ross J, Jones S, Smith A, Harms S., *Impact of a Novel Bioabsorbable Implant on Radiation Treatment Planning for Breast Cancer*, WORLD JOURNAL SURGERY, Feb 2017;41(2):464-471. doi:10.1007/s00268-016-3711-y.

⁹ Ashley Tsang et al., *Maintaining contour with a Three-dimensional interstitial tissue marker in 134 lumpectomies*, PLAST RECONSTR SURG GLOB OPEN, 2021;9: e3696.

14–22 (analysis by Hologic’s epidemiologist expert surveying the literature).

Plaintiffs in this litigation assert that the BioZorb caused them to experience some of the same adverse effects that are commonly associated with breast conserving therapy, including pain, palpability of the device, infections, and/or scarring. In August 2023, Hologic reported a number of Plaintiffs’ litigation complaints to FDA. Prompted by those reports, FDA issued a Safety Communication in February 2024. Ex. K. Following further interactions with the agency, in October 2024, Hologic voluntarily removed the BioZorb from the market, which FDA ultimately classified as a “Class I” product recall. *See* Ex. L.

To be sure, beginning in late 2023, FDA has expressed concerns about the safety of the device based on these reports of adverse events, and has also been critical of some of the company’s internal processes and procedures for regulatory compliance. *See* Ex. M (FDA Warning Letter, 12/18/24). The agency has not, however, presented any data showing that BioZorb is the cause of those adverse effects. Nor has it drawn any conclusion that BioZorb caused those events.

In cooperation with FDA, moreover, the company has been rigorously investigating the potential link between the reported adverse events and BioZorb. While that investigation is ongoing, the company has never concluded that the BioZorb is responsible for the adverse events that are the subject of this litigation. To the contrary, including Plaintiffs in this litigation, complaint rates for the BioZorb have remained consistently low, under 0.5% of units sold. *See* Ex. N at 11–12 (Oct. 2024 Health Risk Assessment).

B. Plaintiff Kimberly Taylor

Kimberly Taylor was diagnosed with cancer in her left breast in May 2021, at the age of 50. Ex. A at 13. On June 8, 2021, Dr. Rache Simmons, a breast surgeon at New York Presbyterian

Hospital, performed a partial mastectomy and implanted a BioZorb device in Ms. Taylor’s left breast. *Id.* Ms. Taylor subsequently participated in a clinical trial of an accelerated radiation regimen, in which she received ten sessions of radiation to her left breast. *Id.*

Ms. Taylor first reported left breast tenderness in August 2021, about six weeks after completing radiation therapy.¹⁰ Ex. O at 1. After that time, her medical records document modest or low levels of pain, ranging from 0 to 4 on a 0–10 scale. *E.g.*, Ex. P at 2 (pain score of 2 out of 10 in Sept. 2021); Ex. Q at 1 (“[l]eft breast is no longer painful” in November 2021); *id.* at 9 (in December 2021, left breast was “normal” with “[n]o . . . mass, . . . skin change, [or] tenderness”); *id.* at 15–16 (in February 2022, “no apparent distress or discomfort noted” and breast is “[w]ell healed”); *id.* at 17 (“[n]o complaints” in April 2022); *id.* at 23 (pain score of 4 out of 10 in July 2022, with a score of 1 out of 10 for the pain’s interference with enjoyment of life); Ex. S at 1 (patient “has no current breast complaints” in September 2022). Ms. Taylor herself described the pain as “a chronic, annoying pain” that “wasn’t ever anything that [she] considered taking, like an NSAID for.” Ex. C at 118:6–12. Nor was she prescribed any pain medication. *Id.* at 282:13–21.

After changing doctors, on October 5, 2022, Ms. Taylor underwent a total mastectomy to remove both her breasts. Ex. A at 14. While Ms. Taylor claims that the main reason for the total mastectomy was the BioZorb (Ex. C at 126:21–128:12), her medical records reflect that she discussed with her new breast surgeon Dr. Mahmoud El-Tamer undergoing a mastectomy to prevent breast cancer recurrence due to genetic test results that concerned her. *See* Ex. R at 1; Ex. S at 1. Dr. El-Tamer likewise testified that Ms. Taylor underwent the bilateral mastectomy to prevent breast cancer recurrence. Ex. E at 39:20–24. Ms. Taylor’s family members also testified

¹⁰ Ms. Taylor also testified that even prior to her breast cancer diagnosis, her breasts hurt “all the time,” which she attributed to her “jacked up” hormones until she underwent an oophorectomy in November 2021. *See, e.g.*, Ex. C at 323:5–18.

that she told them her mastectomy was conducted to avoid a cancer recurrence. Ex. F at 41:4–42:10 (husband James Gale); Ex. G at 36:18–37:9 (daughter Samara Taylor).

C. Plaintiff Beth Deuel

Beth Deuel was diagnosed with right breast cancer in April 2018. Ex. A at 16. On May 18, 2018, Dr. Stephen Cahill, a breast surgeon at McLaren Macomb Hospital in Michigan, performed a partial mastectomy and implanted a BioZorb device. *Id.* at 17. Because her margins still showed evidence of cancer, a second resection was also performed. *Id.* at 18. Following those two surgeries, Ms. Deuel underwent radiation therapy between July and August 2018. *Id.*

Ms. Deuel reported breast pain over the following years, but her medical records and testimony reflect that the pain was sporadic and generally mild to moderate. Ms. Deuel rated the physical discomfort she felt following radiation therapy as a “[o]ne to three” out of ten and occasionally a zero out of ten. Ex. D at 168:18–169:1. In March 2019, Ms. Deuel informed her radiation oncologist that she had “occasional pain at the lumpectomy site in the region of the BioZorb.” Ex. V at 1. In August 2019, however, Ms. Deuel “denie[d] interval breast masses, nipple discharge, inversion, or pain.” Ex. W at 1. In 2020, Ms. Deuel reported left breast pain and “occasional soreness in the right breast, particularly along the surgical scars.” Ex. X at 3. In August 2021, Ms. Deuel’s breast surgeon noted that she was considering a surgery to address breast asymmetry and removal of the BioZorb and that the BioZorb “remains tender.” Ex. Y at 1. However, in January 2022, her breast surgeon noted that the BioZorb was “nontender” and that while she had previously expressed interest in removal of the BioZorb and fat grafting, she wished to hold off in light of her improved developments with weight loss. Ex. Z at 1.

Ultimately, Ms. Deuel nevertheless decided to have an excision surgery, which Dr. Cahill performed on May 17, 2022. Ex. AA at 1–2. The pathology report from that surgery noted surgical

clips but not any remaining BioZorb framework. Ex. BB at 1. Dr. Cahill testified that “there was not really a BioZorb proper that I could identify” in the tissue excised. Ex. H at 100:1–11.

D. Plaintiffs’ Expert Dr. Guy Jones

Dr. Guy Jones is the Medical Director for Oncology Nevada and St Mary’s Regional Medical Centers in Reno, Nevada. Ex. A at 1. Plaintiffs’ counsel retained him through an online service called the “Expert Institute.” See Ex. B at 9:6–18; <http://expertinstitute.com>.

While Dr. Jones opines that the BioZorb marker results in adverse effects, he used no established methodology for conducting a general causation analysis. Dr. Jones instead bases his medical causation testimony largely on his personal experience with approximately 50 BioZorb patients that he saw prior to 2021 in his former practice. See Ex. A at 1; Ex. B at 83:11–17. Specifically, he claims that ten of these fifty patients experienced complications, although “the rest didn’t.” Ex. B at 83:11–17. To ascertain the cause of Ms. Taylor’s and Ms. Deuel’s injuries, Dr. Jones purports to have conducted a “differential diagnosis.” Ex. A at 14–15, 21–22. His differential diagnosis is also based mostly on his personal experience. See *id.*

III. LEGAL STANDARD

Under *Daubert*, an expert’s opinions must be the product of reliable principles and methods. Fed. R. Evid. 702(c), (d); *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589–91 (1993). The recent amendment to Rule 702 “emphasize[s] that expert testimony may not be admitted unless the proponent demonstrates to the court that it is more likely than not that the proffered testimony meets the admissibility requirements set forth in the rule.” Fed. R. Evid. 702 Advisory Comm. Notes to 2023 Amend.; see also *Liberty Mut. Ins. Co. v. Broan-NuTone LLC*, 731 F. Supp. 3d 205, 212 (D. Mass. 2024) (recent amendments emphasize that “each expert opinion must stay within the bounds of what can be concluded from a reliable application of the

expert's basis and methodology"). "The Court must be vigilant in exercising its gatekeeper role because . . . an expert's testimony may be given substantial weight by the jury due to the expert's status." *Bricklayers & Trowel Trades Int'l Pension Fund v. Credit Suisse First Bos.*, 853 F. Supp. 2d 181, 187 (D. Mass. 2012), *aff'd sub nom.*, 752 F.3d 82 (1st Cir. 2014).

The court must also ensure that an expert's opinions are sufficiently rooted in the underlying facts and data. Fed. R. Evid. 702(b); *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). "[A] court may exclude an expert's opinion when it is based upon conjecture or speculation deriving from an insufficient evidentiary source." *Equal Emp. Opportunity Comm'n v. Texas Roadhouse, Inc.*, 215 F. Supp. 3d 140, 158 (D. Mass. 2016). Exclusion is thus justified when "there is simply too great an analytical gap between the data and the opinion proffered." *Rodriguez v. Hosp. San Cristobal, Inc.*, 91 F.4th 59, 70–71 (1st Cir. 2024) (quoting *Joiner*, 522 U.S. at 146).

In a product liability case as this, Plaintiffs must prove that the BioZorb was a proximate cause of their alleged injuries. To do so, Plaintiffs must show not only that the product in question can generally cause the harm alleged (general causation), but also that it caused Plaintiffs' specific injuries (specific causation). *See, e.g., In re Fresenius GranuFlo/NaturaLyte Dialysate Prods. Liab. Litig.*, 691 F. Supp. 3d 280, 298 (D. Mass. 2023) ("[C]ausation is a fundamental element of plaintiffs' claims and 'to prevail in a pharmaceutical personal injury case,' they must proffer evidence of both general and specific causation.") (citation omitted); *In re Neurontin Mktg., Sales Pracs., & Prods. Liab. Litig.*, 612 F. Supp. 2d 116, 123 (D. Mass. 2009) (same). "[T]he issue of medical causation requires expert analysis." *Kerlinsky v. Sandoz Inc.*, 783 F. Supp. 2d 236, 242 (D. Mass. 2011). As set forth below, Dr. Jones' testimony as to both general and specific causation is unreliable, and the Court should exclude both opinions.

ARGUMENT

I. THE COURT SHOULD EXCLUDE DR. JONES' GENERAL CAUSATION OPINIONS

The Court should preclude Dr. Jones from offering a “general cause” opinion (*i.e.*, that BioZorb is associated with an increased rate of adverse effects) because such an opinion is not based on any accepted or reliable methodology. *See, e.g.*, Ex. A at 8–9 (Section IV).

Most often, general causation is established after reviewing the epidemiologic evidence to confirm that an association exists between a product and an injury. *In re Fresenius*, 691 F. Supp. 3d at 291 (citation omitted) (“[G]eneral causation is established by demonstrating, often through a review of scientific and medical literature, that exposure to a [device or] substance can cause a particular [injury].”); *In re Neurontin*, 612 F. Supp. 2d at 125 (“[E]pidemiological studies are often offered as evidence supporting a theory of general causation in the courtroom.”); *Sutera v. Perrier Grp. of Am. Inc.*, 986 F. Supp. 655, 662 (D. Mass. 1997) (excluding causation opinion where “Plaintiffs have produced no scientific peer-reviewed epidemiological studies which would associate” the disease and ingested substance).

Yet Dr. Jones repeatedly disclaimed any reliance on published epidemiologic data concerning BioZorb’s safety profile. Ex. B at 137:15–18 (Q: “Am I correct you can’t cite any epidemiology studies showing an increased risk of pain with BioZorb compared to lumpectomy alone; correct?”; A: “They don’t exist, right.”). Similarly, when asked if he could cite any study that shows BioZorb patients have more severe pain than what typically results from surgery and radiation, Dr. Jones responded that “[t]hose studies don’t exist so I don’t – there’s no comparison there.” *Id.* at 125:14–20. He also could not cite any peer-reviewed publications concluding that the BioZorb is associated with a greater risk of infection than a lumpectomy alone (*id.* at 165:16–

19) or a greater risk of chronic inflammatory response (*id.* at 209:3–7).¹¹

In this Circuit, an expert may also base general causation opinions on the “Bradford Hill” criteria, a series of analytical steps used by scientists to assess the relationship between an alleged causal agent and the claimed injuries. *See Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 17–20 (1st Cir. 2011). But Dr. Jones does not purport to conduct a Bradford-Hill analysis either. When asked by Plaintiff’s counsel what his methodology was, he answered “[y]ou look at everything you can possibly find on the topic and you – you know, you have to kind of take the totality of what you find.” Ex. B at 248:14–249:6. Such an unstructured, gestalt approach is simply not a reliable or recognized method for conducting a general causation inquiry in this Circuit or elsewhere. *See, e.g., In re Zofran (Ondansetron) Prods. Liab. Litig.*, No. 1:15-md-2657-FDS, 2019 WL 5685269, at *12 (D. Mass. Nov. 1, 2019) (granting exclusion where expert “did not apply the Bradford Hill criteria, or any other scientific methodology to assess whether [the product] can cause birth defects”).

What is more, each of the constituent parts of Dr. Jones’ “totality of what you find” opinion are based on an unscientific analysis of unreliable sources of data. **First**, the main input in Dr. Jones’ approach is his own personal experience with BioZorb patients. *See* Ex. A at 8–9 (Section IV); Ex. B at 248:14–249:12 (clinical experience is an “important piece” of his analysis). But Dr. Jones’ personal experience with BioZorb is not a reliable basis for a general cause opinion. Courts routinely exclude expert opinions based on “personal, unscientific observation” such as his. *See*,

¹¹ The only published literature that Dr. Jones cites in Section IV of his report is a case report of a single patient’s experience by Ju et al. *See* Ex. A at 9 n. 15. Yet Dr. Jones admitted that case reports are hypothesis-generating and not proof of causation. *See* Ex. B at 61:16–22 (Q: “But in terms of scientific evidence, [case reports] are hypothesis generating and are not proof of causation; correct?” A: “So they are hypothesis generating. I don’t think very many people would say proof. That’s probably the best I can say, yes.”). *Cf. also* discussion *infra* at 12 (adverse events are not reliable proof of causation).

e.g., *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 604–05 (S.D.W. Va. 2013) (excluding general causation opinion that was “based on nothing more than [the expert’s] personal, unscientific observation and opinion that ‘it’s obvious’ that mesh arms are sharp and can serrate or tear nerves”); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 700–01 (S.D.W. Va. 2014) (excluding general causation opinion based on limited experience in diagnosing fifteen to twenty post-implantation patients); *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 440 (S.D.N.Y. 2016) (excluding causation opinion based on personal observations).

Indeed, Dr. Jones’ experience with BioZorb is completely subjective and untestable. *See Daubert*, 509 U.S. at 593 (“testability” is a key admissibility factor). Dr. Jones claims that he treated approximately fifty patients that were implanted with the BioZorb, and he estimates that while 80% of those patients had no BioZorb-related complications, 10 patients did experience complications including pain. Ex. B at 83:11–17, 124:15–23. Yet Dr. Jones has no actual data or written record reflecting or recording this patient experience. *Id.* at 87:24–90:5. He has never published about it. *See Daubert*, 509 U.S. at 593 (peer review is a key admissibility factor). He did not submit adverse events to FDA at the time his patients supposedly experienced side effects. Ex. B at 90:8–91:7. He has no imaging or any other medical records to document his patients’ conditions. *Id.* at 89:2–5; 22:4–18. His opinion is therefore based completely on his own recollection and subjective assessment. *See Joiner*, 522 U.S. at 146 (district courts must exclude “opinion evidence that is connected to existing data only by the *ipse dixit* of the expert”); *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d at 440 (methodology was “devoid of objective standards that can be tested by others” where expert was “unable to cite support, peer-reviewed or otherwise, that backs his theory”).

Second, Dr. Jones’ use of BioZorb adverse event data to support his opinion is similarly

based on a wholly unscientific and unreliable method. *See* Ex. A at 9; Ex. B at 110:16–19. Courts are, in general, highly skeptical of drawing causation conclusions from adverse event reports because they are simply anecdotes. *See, e.g., Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989–90 (8th Cir. 2001) (“[C]ausal attribution based on case studies must be regarded with caution.”) (quoting *Reference Manual on Scientific Evidence* 475 (Fed. Judicial Ctr. 2000)); *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002) (“[W]hile case reports may provide anecdotal support, they are no substitute for a scientifically designed and conducted inquiry.”) (citation omitted); *Vascular Sols., Inc. v. Marine Polymer Techs., Inc.*, No. CV 05-12092-RWZ, 2008 WL 11429635, at *1 (D. Mass. Mar. 24, 2008) (“[T]he [FDA] complaint records are not the type of evidence reasonably relied upon by experts.”).

That skepticism is borne out here. Dr. Jones did no statistical analysis whatsoever of the reports. *See* Ex. B at 111:5–7 (Q: “Did you do a statistical analysis of the adverse event reports to the FDA?” A: “Not other than reviewing it.”). Indeed, he does not present any written record at all of his work. His method was simply to “read them” and look for commonalities. *Id.* at 111:8–11. He did not consider the rate of adverse events, because he wrongly assumed that data concerning the number of products sold does not exist. *See id.* at 120:4–6; Ex. N at 11 (showing units of product sold). And he made no effort to account for reporting bias, such as identifying reports submitted by lawyers. *See* Ex. B at 111:18–19. Tellingly, before taking on this case, Dr. Jones did not even know that there *was* such a thing as the FDA reporting system. *Id.* at 112:5–8 (Q: “[P]rior to offering opinions in this litigation, you weren’t aware of the FDA adverse event reporting system; correct?” A: “I did not have any idea, nope.”).

Finally, Dr. Jones cannot reliably base a medical causation opinion on FDA’s issuance of a safety communication or its recall of the device. Ex. A at 2. Courts frequently recognize that

government agencies’ preventative action to reduce the risk of potential harm does not equate to causation for tort law purposes. *See, e.g., Glastetter*, 252 F.3d at 991 (“The FDA’s 1994 decision that Parlodel can cause strokes is unreliable proof of medical causation . . . because the FDA employs a reduced standard (vis-a-vis tort liability) for gauging causation....”); *Rider*, 295 F.3d at 1201 (similar); *In re Neurontin*, 612 F. Supp. 2d at 137 (“[T]he decision by the FDA to require warnings on a drug label, without more, does not suffice to establish causation.”); *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 387 F. Supp. 3d 323, 356 (S.D.N.Y. 2019), *aff’d*, 982 F.3d 113 (2d Cir. 2020) (similar). Here, Dr. Jones does not point to any FDA statement drawing causation conclusions. Ex. B at 70:14–22. Instead, though he is not a regulatory expert (*id.* at 47:8–10) and does not know what the definition of a Class I recall is (*id.* at 70:23–25), he believes without support that causation can be “inferred” from the market withdrawal. *Id.* at 70:14–17.¹²

Accordingly, without any reliable method or adequate supporting data, Dr. Jones’ general causation opinion is inadmissible. *See Daubert*, 509 U.S. at 589–91; *Joiner*, 522 U.S. at 146.

II. THE COURT SHOULD EXCLUDE DR. JONES’ DIFFERENTIAL DIAGNOSIS

Unlike for general cause, Dr. Jones does use an established method to assess specific causation: a “differential diagnosis.” But that does not mean his opinion is admissible. Plaintiffs “still must show that the steps taken as part of that analysis—the ‘ruling out’ and the ‘ruling in’ of causes—were [themselves] accomplished utilizing scientifically valid methods.” *Milward v. Rust-Oleum Corp.*, 820 F.3d 469, 476 (1st Cir. 2016). A differential diagnosis is not reliable when an

¹² Dr. Jones also cannot reliably base causation opinions on internal company emails or other documents for the reasons explained below. *See* discussion *infra* at 18–19. *See also* Ex. B at 121:7–10 (admission that no company document reported on the rate of adverse events with BioZorb compared to rates without).

expert “fails to articulate a scientifically reliable basis linking the constellation of symptoms reported by [plaintiff] with [the injury] in order to ‘rule in’ that particular diagnosis” and the differential diagnosis fails to “reasonably survey other potential causes of [plaintiff’s] symptoms.” *G v. Fay School, Inc. by and through its Board of Trustees*, 282 F. Supp. 3d 381, 391 (D. Mass. 2017).

A. Dr. Jones Does Not Reliably “Rule In” BioZorb

Dr. Jones utterly fails at the first step of a differential diagnosis: to reliably “rule in” BioZorb as a potential cause of Plaintiffs’ injuries. For all the reasons set forth above, he has no reliable methodology on which to base an opinion that the rates of adverse effects are any greater for patients with BioZorb than for breast cancer patients who have not had the device implanted. *See supra* Section I. Nor can other of Plaintiffs’ experts supply this missing piece, as Dr. Jones nowhere states that he has relied on any other expert’s report, and in any event, an “expert must do more than ‘parrot’ another expert’s conclusions.” *Cashman Dredging & Marine Contracting Co., LLC v. Belesimo*, 759 F. Supp. 3d 120, 156 (D. Mass. 2024). Without a scientifically reliable basis to “rule in” BioZorb as a potential cause of Plaintiffs’ injuries, Dr. Jones’ differential diagnosis is flawed at the outset and should be excluded for this reason alone.

B. Dr. Jones Does Not Reliably “Rule Out” Other Potential Causes

Dr. Jones also fails at the second step of the differential diagnosis: to reliably “rule out” other potential causes of Plaintiffs’ injuries.

1. Plaintiff Kimberly Taylor

At bottom, Dr. Jones’ “ruling out” of breast surgery and radiation therapy as the cause of Plaintiff Taylor’s pain boils down to his assertion that her pain is 1) more persistent than the ordinary course of radiation-induced pain; and 2) localized to the site of the BioZorb, where there

is a palpable lump. Ex. A at 15. Neither is based on reliable methodologies or data.

First, Dr. Jones has no reliable basis to opine that the “persistence” of Plaintiff Taylor’s pain differentiates it from pain commonly reported after lumpectomies and radiation treatment. Dr. Jones admits that “chronic pain” can result after a lumpectomy and radiation therapy in breast cancer patients who did not have a BioZorb implanted. Ex. B at 125:5–8 (Q: “[C]hronic pain, you agree, can occur after a lumpectomy and radiation without BioZorb; correct?” A: “It’s documented, yes.”); *id.* at 134:8–10 (Q: “Do you agree that patients can experience persistent and chronic pain after a lumpectomy”; A: “I -- Yes”). Indeed, literature shows that over a third of breast cancer patients reported “persistent pain” five to seven years post-treatment and almost a quarter of patients who received accelerated radiation treatment reported experiencing pain five years post-treatment. *See supra* at 2 and nn. 3–5.

Eschewing this data, Dr. Jones instead emphasized a study called the “UK IMPORT LOW” trial. Ex. B at 257:11–258:12. But even that trial noted that 4–5% of patients who underwent radiation therapy were still experiencing breast pain after five years. *Id.* at 274:19–275:8. And it reported a 5-year cumulative incidence rate of pain (meaning reported pain at some point during the study period) of between 16.9–19.1% -- which approximates the same “rate” of complications that Dr. Jones observed in his own BioZorb patient population. *Id.* at 275:17–21. What is more, Plaintiff Taylor’s pain did not last five years. It began after her radiation therapy concluded in August of 2021, and she underwent her bilateral total mastectomy less than a year-and-a-half later in October 2022. *See supra* at 5. That is years shorter than the five-year time point addressed in the IMPORT trial on which Dr. Jones relies.

Second, Dr. Jones’ reliance on the fact that Ms. Taylor’s pain was at the site of the BioZorb implantation ignores the fact that her lumpectomy procedure and radiation therapy targeted that

same area. Dr. Jones thus admitted that localized pain occurs in the absence of the BioZorb following a lumpectomy and radiation therapy. *See* Ex. B at 136:1–3 (“Q: So localized pain does happen in the absence of BioZorb; correct?”; A: “It does, yes.”). He contended instead that localized pain is “more common” with the BioZorb. *Id.* at 135:18–25. But this assertion is backed up only by his anecdotal experience, unsupported by any published medical authorities.

The medical evidence does not support Dr. Jones’ opinion either. Dr. Jones states that “post-surgical pain from lumpectomy most often persists at the site of the external incisions,” Ex. A at 15, but that is the exact location where Ms. Taylor’s medical records often note pain. On June 2, 2022, Ms. Taylor’s oncologist noted “pain ***overlying incision***” (Ex. T at 1) (emphasis added), and on July 11, 2022, Ms. Taylor’s breast surgeon similarly noted “[l]eft breast pain ***overlying breast incision.***” Ex. U at 1 (emphasis added). In addition, her pain complaints were not limited to “localized” pain. Ms. Taylor testified that from adolescence, her “breasts hurt all the time” and that she “didn’t realize that you could have breasts that didn’t hurt until post my oophorectomy.” Ex. C at 285:1–286:6. Even after her oophorectomy, in June 2022, her oncologist Dr. Jacqueline Bromberg noted “extreme density of left breast and tenderness ***throughout*** breast.” Ex. T at 4; *see also* Ex. C at 336:14–337:11 (Ms. Taylor testified that she experienced tenderness throughout the breast on a regular basis).

2. Plaintiff Beth Deuel

Dr. Jones’ differential diagnosis for Plaintiff Beth Deuel is equally unreliable.

First, Dr. Jones relies on the fact that Ms. Deuel’s symptoms resolved “immediately after removal of the BioZorb device” (Ex. A at 22). But Ms. Deuel’s medical records contain no indication that any portion of the BioZorb’s framework was still present by the time of her excision surgery. *See supra* at 6–7. Dr. Jones admitted at his deposition that he was basing his “causation

opinion for Miss Deuel . . . at least in some part on the fact that there are plastic pieces noted in the medical records” at the time of Ms. Deuel’s excision surgery. Ex. B at 245:3–6. There are no such records.

Dr. Jones also asserts that Ms. Deuel’s pathology report “demonstrated inflammatory changes which is generally associated with pain.” Ex. A at 22. However, he provides no reliable basis for ruling out radiation therapy and breast surgery as the cause of any inflammatory changes. In particular, he admits that fibrosis can result from a lumpectomy and radiation and “is characterized by scar-tissue-like formation of fibrous connective tissue” that “can be associated with feelings of ‘tightness,’ discomfort, and pain in the affected area.” Ex. A at 11; Ex. B at 101:23–25, 236:13–15.

Second, the fact that “the site of [Ms. Deuel’s] BioZorb continued to be painful years after placement” is not a basis on which to rule out Ms. Deuel’s partial mastectomy and radiation therapy as the source of her pain. As already discussed with respect to Ms. Taylor, chronic pain can result from radiation, and studies have found that patients can experience long-term pain after breast surgery and radiation therapy. *See supra* at 15.

Dr. Jones also improperly rules out radiation therapy on the basis that Ms. Deuel’s pain allegedly “began prior to her radiation therapy.” Ex. A at 22. This fails to account for the fact that Ms. Deuel could have experienced both post-surgical and post-radiation pain, which is not uncommon. *See discussion supra* at 15. Dr. Jones did not dispute that Ms. Deuel’s reports of pain became more frequent in the months following radiation therapy. *See* Ex. B at 236:16–22.

Third, Dr. Jones’ assertion that “Ms. Deuel’s discomfort was always associated with the BioZorb device itself” ignores that Ms. Deuel could experience localized pain in the area of her lumpectomy and radiation treatment irrespective of BioZorb. Again, Dr. Jones acknowledged that

localized pain occurs without BioZorb. *See* Ex. B at 136:1–3; discussion *supra* at 15–16.

Fourth, Dr. Jones admitted that Ms. Deuel’s medical history is significant for Type 2 diabetes mellitus and obesity, and that these factors increased her risk of complications, including pain and inflammation. Ex. B at 72:21–25, 243:5–9, 243:18–20. In fact, he admitted that these factors (as well as the multiple resection surgeries she had) *did* contribute to her complications. *See id.* at 72:21–25 (“Q: And for Ms. Deuel, what are the other factors that contribute to her complications?” A: “So her diabetes and her reresection and – you know, I’m going to say diabetes and obesity and her reresection.”).

In sum, because Dr. Jones’ differential diagnoses fail to reliably “rule out” alternative causes for both Ms. Taylor and Ms. Deuel, his specific causation opinions should be excluded. *See Milward*, 820 F.3d at 476.

III. THE COURT SHOULD EXCLUDE DR. JONES’ OPINIONS CONCERNING MARKETING AND OTHER COMPANY DOCUMENTS

Dr. Jones testified that he intends to offer opinions regarding Hologic’s marketing of the BioZorb, including “the effects of [Hologic’s] misleading marketing.” Ex. B at 181:23–182:2, 194:1–6. Likewise, he repeatedly cites to internal company documents to express various opinions, including that Hologic failed to disclose information or acted improperly. *See, e.g.*, Ex. A at nn. 8–14; Ex. B at 175:3–9. These opinions should be excluded for multiple reasons.

First, as a radiation oncologist, Dr. Jones is not qualified to offer opinions concerning Hologic’s marketing or other company documents. *See* Fed. R. Evid. 702. He admits that he is not an expert in medical device regulations, including marketing regulations. Ex. B at 47:11–16. He has never worked for FDA. *Id.* at 47:2–3. Nor, unsurprisingly, does he have any training or experience in interpreting internal company documents. *Id.* at 172:11–20.

Second, his marketing opinions are not based on any reliable methodology and simply do

not fit the facts of this case. His methods consisted simply of reviewing select marketing materials that Plaintiffs’ counsel provided him. *See* Ex. B at 183:11–15 (“I looked at everything I could find that was sort of given to me . . .”); *id.* at 186:12–15 (“The method is to look through all of it . . .”). In doing so, he relied on draft marketing materials, for which he had no evidence of actual distribution to doctors in the field. *Id.* at 175:3–9. And Dr. Jones made no attempt to determine what, if any, marketing Plaintiffs’ particular doctors saw or heard. *Id.* at 187:16–20 (“You can’t tell me what was marketed to the physicians who treated Miss Taylor or Miss Deuel; correct?” A: Yes, I don’t know who those doc—who those marketers were.”); *see also Hager v. Vertrue, Inc.*, No. 09--11245--GAO, 2011 WL 4501046, at *1 (D. Mass. Sept. 28, 2011) (excluding expert opinions “not relevant” to the plaintiff in the case).

Third, Dr. Jones should not be able to testify based on company documents to tell a story that Hologic “acted badly” or with ill motives. No expert is qualified to opine on a party’s intent, motive, or state of mind. *See, e.g., Cashman Dredging*, 759 F. Supp. 3d at 160 (“It is well-established that ‘[i]nferences about the intent or motive of parties or others lie outside the bounds of expert testimony.’”) (citation omitted); *In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) (“[T]he opinions of these witnesses on the intent, motives or states of mind of corporations . . . and others have no basis in any relevant body of knowledge or expertise.”). And courts routinely find that narrative testimony based on company documents is not the proper province of expert testimony. *See In re Zofran*, 2019 WL 5685269, at *9; *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1337 (S.D. Fla. 2010); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009). The fact witnesses who were involved in writing, sending, or receiving these documents are the proper witnesses to be examined, either on direct or cross, about these documents. No expert assistance is needed for the jury to understand them.

CONCLUSION

For all the reasons set forth herein, the Court should exclude Dr. Jones' opinions on general causation, specific causation, and Hologic's marketing of the BioZorb.

Respectfully submitted,

June 6, 2025

HOLOGIC, INC.,
By its attorney,

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LOCAL RULE 7.1 CERTIFICATION

In accordance with the requirements of Local Rule 7.1(a)(2), I hereby certify that counsel for the Defendant conferred with Plaintiffs' counsel regarding this motion, but was not able to reach any agreement on this motion.

/s/ Daniel P. Tighe
Daniel P. Tighe

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the NEF (NEF) and paper copies will be sent to those indicated as non-registered participants on June 6, 2025.

/s/ Pietro A. Conte

Pietro A. Conte